

February 27, 2013

Via ECF

Honorable F. Dennis Saylor, IV
United States District Court
John Joseph Moakley U.S. Courthouse
1 Courthouse Way, Suite 2300
Boston, Massachusetts 02210

RE: *In Re: New England Compounding Pharmacy, Inc.*
MDL 2419; C.A. No.: 13-md-2419-FDS

Dear Judge Saylor:

This letter responds to this Court's request of February 15, 2012 that any plaintiff's counsel wishing to do so may file a letter, not to exceed four pages, addressing the form of an organizational structure for plaintiffs' interests in *In Re New England Compounding Company Products Liability Litigation*, MDL No. 2419.

The proposal. Reasonable minds may differ on this topic. The typical pharmaceutical mass tort MDL has between ten and twenty firms serving in appointed roles. But this MDL is far from typical. We believe that the unique challenges of the NECC meningitis outbreak warrant the formation of a streamlined five person plaintiffs' steering committee comprised of a sole lead counsel, a federal-state liaison and three other members. While this is somewhat larger than the committee structure remarked upon by the Court at the February 15 hearing, it is markedly smaller than many other mass tort MDL organizational structures.

We first outline the work ahead and the challenges to bring the largest return to victims in the shortest amount of time and with the least amount of expense. We then turn to the proposed structure, and the reasons we think, on balance, a streamlined structure makes the most sense.

The situation, in brief. This MDL arises out of the tragic, fast-paced outbreak of fungal meningitis first reported last September to be caused by contaminated NECC products. The Centers for Disease Control have identified over 700 infections¹ and 47 deaths² in patients exposed to NECC's preservative-free methylprednisolone acetate ("MPA") injection. All NECC and Ameridose products were recalled. Both companies have suspended product distribution.

The tragedy has been widely reported in the press, due to the shocking nature of its scope, the immediacy from cause to effect (injection leading to rare infection), and the failure of adequate regulatory supervision for basic sanitary conditions. Governmental, congressional and

¹ The reported infections go beyond fungal meningitis itself. The CDC continues to receive reports of patients presenting with paraspinal/spinal infections (e.g., epidural abscess, phlegmon, discitis, vertebral osteomyelitis, or arachnoiditis at or near the site of injection). These syndromes have occurred in patients with and without evidence of fungal meningitis.

² Deaths reported are from all causes among persons who meet the case definition and may not be directly attributed to a fungal infection.

criminal investigations of NECC and related persons have begun. The press reports witnesses are testifying before grand juries. These are but a few of the factors complicating the discovery phase of the pending civil proceedings.

Almost immediately upon the recognition of the outbreak, a vast number of civil suits were filed. Most of these name NECC as a defendant. Some named additional defendants, including (i) the individual principals of NECC, (ii) other NECC-related entities, including Ameridose, Medical Systems Management, GDC Properties, and other companies owned and operated by the same individuals that owned and operated NECC, (iii) contractors, subcontractors, cleaning companies, and others responsible for the conditions in the clean room and related facilities in which the contaminated products were made, (iv) the testing company and others responsible for assuring product quality, and (v) pain clinics, hospitals, and health care providers.

Late last year, before any discovery other than this Court's ordered inspection of the facilities had begun, NECC filed for Chapter 11 bankruptcy. In January, the U.S. trustee (a) appointed a nine member official creditors' committee – including eight tort claimants and their representatives from many states – to represent the interests of all creditors (primarily comprised of the tort claimants) and, (b) after obtaining approval from the United States Bankruptcy Court for the District of Massachusetts, appointed a trustee to run NECC's affairs (the "bankruptcy trustee").

The Judicial Panel on Multidistrict Litigation subsequently ordered product liability cases in which NECC is a party transferred to this district for coordinated pretrial proceedings. The Panel has not yet decided whether outbreak-related actions not naming NECC itself will be grouped into the MDL. Numerous cases remain pending in state courts (having not been removed, or remanded after removal), predictably in states where the outbreak had its greatest impact.

The unique challenges we face. It is generally accepted that any available assets from NECC and potentially responsible NECC-related parties (i.e., the individual owners and related companies) will be substantially insufficient to fully compensate the tort claimants, creating as to these parties a limited fund. This situation presents challenges to the civil justice system, the legal profession, and the judiciary of large and difficult proportions under a spotlight of warranted and intense public scrutiny. Can the judicial system achieve reasonable and prompt payment to victims? Can compensation be achieved in this limited fund situation without the assets being dissipated by unnecessary legal disputes, or large fees and expenses? Can non-liable defendants receive justice, and can liable defendants pay fairly and receive a binding release to obtain peace from later claims?

To us, getting to "yes" depends, in large part, upon having a streamlined plaintiffs' leadership structure.

Not a classic mass tort MDL. The traditional mass tort requires amassing a large amount of financial and human resources to take on an even-better-financed, well-represented, multinational corporate defendant. Discovery usually entails millions of pages of documents,

dozens of depositions, in search of proof of wrongdoing occurring in a large corporate defendant over many years, as well as proof of often nuanced scientific questions of cause and effect. It is no wonder that, from the outset, most mass tort MDLs have large plaintiffs' organizations (9, 12, or many more members) to help finance the operation and provide a voice for the many working hands over many years. A larger group, pooling its resources, is better able to take on well-funded defendants and to overcome a defense strategy of attrition, justifying the investment into a larger PSC, with the expectation that its size and resources will yield an enhanced recovery for tort victims.

But this is not a classic mass tort situation. Here, the core defendant NECC is a small, family-owned, now bankrupt company. Much of the work in collecting and maximizing assets of NECC (including its cash, insurance, physical assets and proceeds from insider claims) for distribution to victims will be undertaken by the bankruptcy trustee and the creditors' committee under the supervision of this Court or the bankruptcy court. There are limited NECC documents to discover – and all of them are currently, or soon to be, in the hands of the bankruptcy trustee. Depositions of NECC will be relatively few and far between (for those who choose not to assert the Fifth Amendment). Assertion of liability against the NECC individuals may be more effectively accomplished by bankruptcy trustee efforts – witness, for example, the result to date of clawback efforts revealing millions of dollars in real estate, cash and investment assets of NECC principals recently frozen by the bankruptcy court. A larger PSC will not increase this asset pool or enhance the net recoveries of the victims.

We do not know the complete “who, what or when” of litigation for this MDL. For example, plaintiffs' lawyers do not appear to have reached a consensus (and the JPML has not decided) as to whether the medical providers (e.g., pain clinics and doctors) should be included as tag along actions in the MDL. A smaller committee can always be enlarged if circumstances warrant, through the addition of sub-committees or by expanding the existing structure to add capacity; it is far more difficult to reduce a committee's size once constituted. At this stage, simple and lean is the way to go.

Much of the work of developing and pursuing claims against some non-NECC defendants can and should be done by lawyers in states, such as Tennessee and Michigan, where the claims are clustered in state court proceedings (hence the importance of a federal/state liaison), or, should the federal cases come to the MDL, through state-specific task forces or working groups, since differences in state law claims and remedies enabling functional lawyer groups with the autonomy to pursue such independent and additional sources of recovery. A streamlined PSC does not supplant or preempt such an approach.

This is a 19th century tort in the 21st century world – an obviously contaminated product that relatively quickly caused substantial injuries as a result of that contamination. This case has relatively little need to delve into science with experts to prove a drug is less effective than promised, or show the mechanism of the action for causing deaths. To be sure, there are some of these issues (for non-fungal cases, for exposures to lots other than the three identified by the CDC, for other defective products, etc.), but the case remains, at this time, simpler than many other situations. A smaller, five-firm committee with a single firm in charge can most efficiently address the exigencies known at this time. And as the needs arise, the significant talents of many

from the mass tort bar can be called upon, but in a way tailored to the specific needs (e.g., particular defendants, products, etc.). Plaintiffs' steering committees commonly use lawyers outside their own ranks – this case calls out for the selective use of doing so.

Not a simple mass tort bankruptcy. By the same token, this is not a simple mass tort bankruptcy where resolution entails a single, or single group, insolvent defendant using almost exclusively bankruptcy proceedings to corral assets, create a distribution plan, and pay out claims. This case presents multiple, mostly under- or modestly financed non-debtor defendants often scattered throughout the country and facing differing prospects for liability. The bankruptcy court's jurisdiction over some defendants is uncertain. These potential liabilities will likely not all be resolved in a single, quick bankruptcy-supervised tort trust without federal court litigation to incentivize all potentially liable defendants to contribute to a joint trust.

The practical, dare we say economic, considerations. MDL steering committees commonly get compensated through a modest percentage of the total recovery in a court-ordered process to award fees to those lawyers who provided services for the common benefit. Two challenges here warrant the smaller structure with clear leadership. First, the limited assets mean the total recovery, despite the best of efforts, must be predicted to be modest; the resulting small percentage of that recovery will also be modest. Austerity is a necessity. Second, the parallel efforts of the bankruptcy trustee (and his counsel, and his consultants) as well as counsel for the creditors' committee will impose expenses upon the total available assets that will further reduce victim recoveries. And, as in most mass torts, victims will also be obligated to pay their individual counsel on their existing, typically contingent fee, contract. A smaller organization is needed to preserve as much of the recovery for the victims.

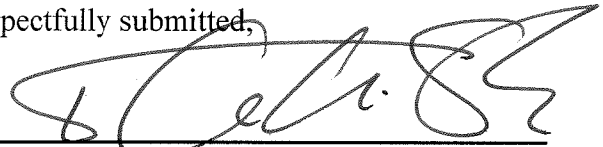
Final remarks. The coordination required between the MDL, the bankruptcy court, and the various state court proceedings warrants, indeed necessitates, a smaller structure within the MDL to best accomplish the goal of efficiently transferring as much of the proceeds as possible to those hurt by the defendants' conduct. The bankruptcy trustee ought to have a singular voice speaking for the MDL plaintiffs in order to most efficiently do his work. And both this Court and all other stakeholders should have a small group to hold accountable.

Geographic diversity is important particularly where, as here, the harm is felt with more vengeance in few states. We recognize that this case has instilled in many lawyers a keen interest to participate – the directness and brute force of the harm evokes a “need to do justice” in many. So those talents should and will be harnessed, over time, and when really needed. But there is already a creditors' committee comprised of eight tort claimants from seven different states. Duplicating the same committee structure here is unnecessary from both a cost and efficiency perspective. The MDL is best served by a strong central leadership who will more effectively coordinate between the bankruptcy court and the state courts.

We respect the views of others that favor a larger committee. A larger committee would normally be ideal; this situation is far from ideal. There is no “right” number. Here, in the end, the primary defendant's assets and insurance are severely limited relative to the severity and number of claims, and the other potentially responsible parties also have limited assets. The values of economy and efficiency are paramount. They counsel in favor of a smaller formal

leadership structure.

Respectfully submitted,



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